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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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09/558,576 04/26/00 WHITSETT M.D.

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EXAMINER

SCHNIZER, H

ART UNIT

PAPER NUMBER

1653

DATE MAILED:

10/02/01

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Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

FILE COPY
09/558,576

Office Action Summary

Applicant(s)

WHITSETT M.D., JEFFREY A.

Examiner

Holly Schnizer

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1653

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 25 July 2001.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 4-6, 8, 10 and 29-34 is/are pending in the application.
- 4a) Of the above claim(s) 4-6 and 8 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) 10 and 29-34 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s) _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ 6) ☐ Other: _____

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DETAILED ACTION

Status of the Claims

The following is a clarification of the pending claims:

In the Response to the Restriction Requirement filed Dec. 18, 2000 (Paper No. 6), Claims 1-3, 7, 9, and 11-24 were cancelled (see p. 1) and Claims 29-34 were added (see p. 2).

Therefore, Claims 4-6, 8, 10, and 29-34 are now pending.

Claims 4-6 and 8 are withdrawn from further consideration as being drawn to a non-elected invention.

Claims 10 and 29-34 have been examined on the merits in this Office Action.

Rejections Withdrawn

The rejection of Claims 10 and 30-32 under 35 U.S.C. 102(e) as being anticipated by Taeusch (U.S. Pat. No. 6,180,142) is withdrawn in light of Applicants' arguments.

The rejection of Claims 10 and 29-34 under 35 U.S.C. 103(a) as being unpatentable over Taeusch in view of Ariizumi et al. (U.S. Patent No. 6,046,158) is withdrawn in light of Applicant's arguments.

New Rejections

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 10, 30-32, and 34 are rejected under 35 U.S.C. 102(b) as being anticipated by Johansson et al. (Eur. Respir. J. (1994) 7: 372-391).

Johansson et al. review the structure and molecular biology of surfactant proteins and their role in clinical use. Johansson et al. state “[h]uman surfactant, isolated from amniotic fluid by sucrose gradient centrifugation, as described by HALLMAN et al. [293], has been used mainly in Finland and California. It contains, apart from lipids, approximately 6% proteins, including hydrophilic (SP-A, SP-D, and nonsurfactant proteins), and hydrophobic polypeptides (SP-B, SP-C)” (see p. 381, paragraph 2). Therefore, it appears that Johansson et al. meet the limitations of the claims.

Claims 10, 30-32, and 34 are rejected under 35 U.S.C. 102(b) as being anticipated by Jobe et al. (Am. Rev. Respir. Dis. (1987) 136: 1256-1275).

Jobe et al. review the characteristics of surfactants and their use in the treatment of respiratory distress syndrome (RDS). Jobe et al. teach that human surfactant from amniotic fluid (which inherently contains SP-D, SP-A, SP-B, SP-C) has been used in clinical trials for the treatment of RDS (see p. 1269, Col. 1-2, “*Human Surfactant from*

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Amniotic Fluid" and p. 1267, Table 5). Thus, it appears that the claims are anticipated by Jobe et al.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 10 and 29-34 are rejected under 35 U.S.C. 103(a) as being unpatentable over Johansson et al. (Eur. Respir. J. (1994) 7: 372-391) in view of Jain-Vora et al. (Infection and Immunity (Sept. 1998) 66(9): 4229-4236).

Johansson et al. teach a pharmaceutical composition comprising SP-A, SP-B, SP-C, and SP-D (see p. 381, paragraph 2) and an excipient. Johansson et al. also teach that SP-D and SP-A play a role in the host-defense system of the lung (p. 377, Col. 1, last 3 lines of first paragraph). Johansson et al. suggest that exogenous surfactant preparation may influence the response to replacement therapy in babies with pneumonia (p. 382, col. 2, 2nd paragraph, line 4-7) and points to a study showing that natural surfactant extract and human amniotic fluid (containing SP-A, SP-B, SP-C, SP-D as discussed on p. 381, second paragraph of Johansson et al.) instilled into the airways of bacterially infected newborn rabbits prevents an increase in bacterial proliferation as compared to a control not receiving the surfactant (p. 382, Col. 2, lines 13-15).

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Jain-Vora et al. teaches that IL-4 is involved in bacterial host defense system by enhancing pulmonary clearance of bacteria (see title and p. 4230, last lines of Introduction). Jain-Vora et al. teaches that surfactant proteins, SP-A and SP-D also play an important role in host defense against bacterial pathogens by stimulating macrophage chemotaxis and enhancing binding of bacteria to macrophages (p. 4234, Col. 2, 2nd paragraph). The Jain-Vora et al. suggest that IL-4 protection from bacterial infection was conferred independently from SP-A and SP-D (p. 4234, Col. 2, last sentence of second paragraph).

Therefore, it would have been obvious to one of ordinary skill in the art at the time of the invention to improve the pharmaceutical composition of Johansson et al. containing the surfactant proteins by adding IL-4 since both are well known to be important in clearance of bacteria from the respiratory tract. One of ordinary skill at the time of the invention would have been motivated to modify the composition of Johansson et al. by adding IL-4 because Jain-Vora et al. teach that IL-4 protection is independent from that of the surfactant proteins and thus it would have been expected that addition of IL-4 to the surfactant composition of Johansson et al. would further enhance the efficacy of the composition. Thus, the claimed invention appears to be unpatentable over the prior art.

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Conclusions

Related art cited but not relied upon:

McCormack (Sem. Respir. Crit. Care Med. (1995) 16(1): 29-38) is an additional reference that provides evidence that SP-D is contained in amniotic fluid (p. 35, Col. 2, lines 10-12) and that skilled artisans at the time of the invention were well aware that surfactant proteins such as those presently claimed could be used as pharmaceutical compositions in the treatment of RDS and bacterial infections such as pneumonia (p. 36, Col. 2, lines 4-9).

No Claims are allowable.

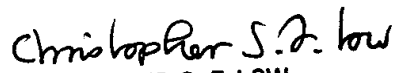
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Holly Schnizer whose telephone number is (703) 305-3722. The examiner can normally be reached on Mon. & Thurs., 8am-5:30pm and Tues. & Wed. 9-2:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christopher Low can be reached on (703) 308-2923. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 308-4242 for regular communications and (703) 308-4242 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.



Holly Schnizer
October 1, 2001



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